FDA 510(k) Premarket Notification

# K211107 BTL-899 FP

**CLEARED**

Jul 9, 2021
86 days to decision

K211107 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211107/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Apr 14, 2021 |
| Decision date | Jul 9, 2021 |
| Days to decision | 86 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

**APPLICANT**

| | |
|---|---|
| Company | **BTL Industries, Inc.** |
| Location | Malborough, MA, US |
| Contact | David Chmel |
| Website | https://www.btlnet.com |
| 510(k) history | 41 submissions · 41 cleared · 2010-2026 |

BTL Industries, Inc. is a medical device manufacturer based in Marlborough, US. The company develops therapeutic and rehabilitation technologies across multiple clinical specialties. BTL Industries has received FDA 510(k) clearances from total submissions since its first clearance in 2010. The company maintains active regulatory status, with its most recent clearance in 2026. Device clearances span General & Plastic Surgery, Physical Medicine, Dental, Neurology, and Gastroenterology & Urology specialties. The company's product portfolio includes robotic rehabilitation sys...